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	Process Owner <b>Management Analyst CIP Department</b>		Approval Authority <b>Head, CIP Department</b>

## 1. Purpose & Scope

This process defines the method of verifying compliance with the program of protection of human research subjects in Navy Clinical Investigation Program. This process applies to all Navy CIP human subject research.

## 2. References

The following documents are either required or helpful to perform the set of tasks in the accompanying flowchart; a) NSHS-002, Quality Systems Document Control, b) NSHS-004 Corrective & Preventive Action, c) 10 US Code 980, d) The Nuremberg Code, e) The Belmont Report "The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research", f) 32 CFR Part 219 "Federal Policy for the Protection of Human Subjects; Notices and Rules", g) DODD 6000.8 "Funding and Administration of Clinical Investigations Programs", h) DODD 3216.2 "Protection of Human Subjects in DOD-Supported Research", i) SECNAVINST 3900.39 "Protection of Human Subjects", j) BUMEDINST 6000.12 "Clinical Investigation Program", k) BUMEDINST 6710.69 "Use of Investigational Agents in Humans", l) NSHSBETHINST 6000.41 "Clinical Investigation Program"

## 3. Definitions

The terms listed below are defined to assist the reader.

- 3.1 Clinical Investigation Department (CID) - Each CID will act as local or regional program manager for clinical investigations within its area of responsibility. The Commander/Commanding Officer of each medical treatment facility and dental treatment facility with a CID has responsibility for the implementation of his/her local program.
- 3.2 Clinical Investigation Program (CIP) - the system of directives, offices, and personnel that enable clinical research within the Department of the Navy.
- 3.3 Clinical Investigation Program Research - a research program, project, task, test, experiment, record review, evaluation, or similar undertaking that uses data collected from DoD health care beneficiaries, laboratory animals, or in vitro to study the maintenance of health or the prevention, alleviation or cure of disease, and whose primary purpose is designed with the intent to develop or contribute to generalized knowledge.

## 4. Document Review & Concurrence

Title of Reviewer	Functional Directorate	Signature & Date	Title of Reviewer	Functional Directorate	Signature & Date
Program Assistant	OP6 (Process Owner)	Ms. S. Ross	Head, CIP Department	OP6 (Approval Authority)	CAPT P. Kent
Management Analyst	OP6	Ms. E. Cooper			

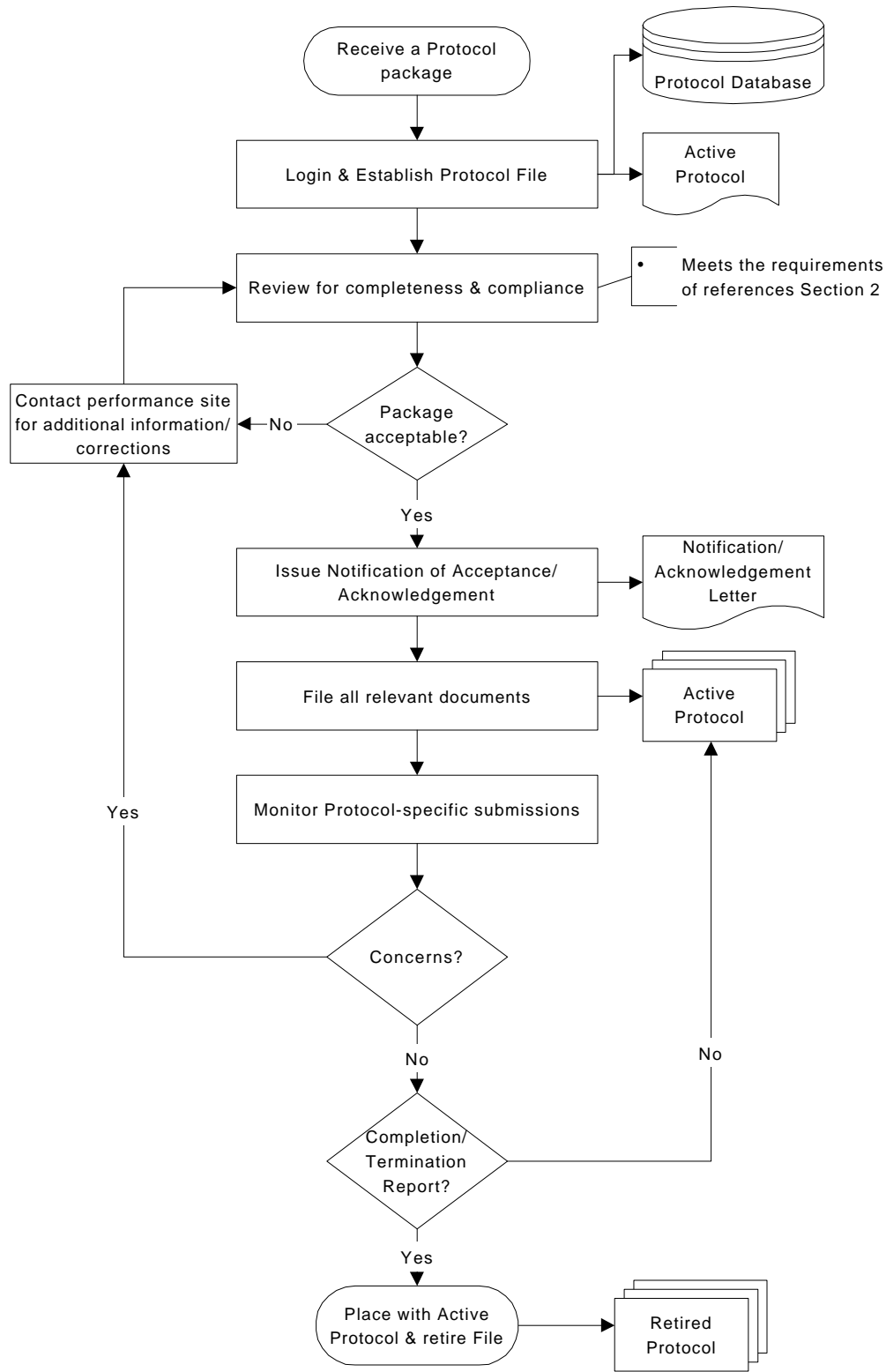
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## 5. Summary of Changes

<i>Version</i>	<i>Description</i>	<i>Date</i>
01	Initial issue of procedure.	17 MAY 01

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## 6. Process Flowchart



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## 7. Quality Records

<i>Record Name</i>	<i>Owner</i>	<i>Location</i>	<i>Indexing</i>	<i>Duration</i>	<i>Disposition</i>
Protocol Database	Management Analyst	Database	By Protocol number	Permanent	SECNAVINST 5212 series
Active Protocol	Management Analyst	File Cabinet	By Protocol Number	Until completed or terminated	SECNAVINST 5212 series
Retired Protocol	Management Analyst	CIP Archive	By Protocol Number	Permanent	SECNAVINST 5212 series

## 8. Addendum

N/A